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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,114	02/09/2001	Tsutomu Nobori	02307O103031	8926
20350	7590	01/29/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			GOLDBERG, JEANINE ANNE	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/780,114	NOBORI ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Pri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the papers filed October 21, 2003. Currently, claims 23-38 are pending.
2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.
3. Any objections and rejections not reiterated below are hereby withdrawn in view of the amendments to the claims or applicant's remarks.
4. The Katz-type declaration has been thoroughly considered and found persuasive.

Priority

5. This application claims priority to 09/072,914, 08/827,342, 08/459,343, 08/176,855.

With respect to Claim 23-38, the Claim is awarded priority to the filing date of 3/26/97 for the invention of a nucleic acid sequence having SEQ ID NO: 1 which encodes the MTase. The 08/459,343 application, filed 6/2/95, which is a divisional of 08/176,855. disclosed SEQ ID NO: 1 containing a partial genomic sequence of the MTase gene and therefore did not encode MTase (since it did not contain all of the sequences indicated as coding sequences in Figure 1 and SEQ ID NO: 1 of the present application). As seen below, neither the instant nor the priority documents appear to discuss or teach particular exon probes of less than 500 bp (see New Matter rejection below).

R sponse to Arguments

The response traverses the date of priority. The response asserts that the priority will be extended back to the earliest related application, namely December 1993. This argument has been reviewed but is not convincing for the reasons set forth in the new matter rejection below. Therefore, the instant claims receive benefit to March 26, 1997.

Thus for the reasons above and those already of record, the date of priority is maintained.

New Grounds of Rejection Necessitated by Amendment

6. 23-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 23, 25, 27, 29, 31, 33, 35, 37 are drawn to an isolated polynucleotide which hybridizes under stringent conditions to a nucleotide sequence comprising X nucleotides of SEQ ID NO: 1 wherein the isolated nucleic acid is less than 500 nucleotides long." The amendment proposes that the new claim language is supported on page 4, 33, and in the original claims. However, the specification does not describe or discuss probes of less than 500 nucleotides or exon probes.

With respect to the length limitation, the specification states, "for the most efficient amplification of DNA fragment by PCR for diagnostic purposes, its size should be preferably less than 500 bp." This passage in the specification is not directed to

particular polynucleotide lengths. The specification does not appear to have contemplated probes in particular regions which hybridize under the particular conditions with less than 500 bp. The example given amplifies sequence using PCR, the fragments are then run on a gel to separate and analyze the products. There is no contemplation that these 500 bp fragments hybridize under stringent conditions to SEQ ID NO: 1. The amplicons contemplated by the specification are not disclosed to hybridize as probes to a particular sequence. There is no disclosure in the specification of probes with less than 500 base pairs.

With respect to exon probes, the specification describes a method for detecting a polynucleotide inside the MTase protein coding domain of the mammal's genome..." (page 4, lines 8-11). This paragraph does not contemplate using exon probes. The skilled artisan would not recognize that applicant's invention was directed to exon probes. While the specification has underlined the exons in the figure, there is no support for nucleic acids consisting of exons, as required by Claims 26, 28, 30, 32, 34, 36, 38.

This description does not support an isolated polynucleotide which hybridizes under stringent conditions to a nucleotide sequence comprising X nucleotides of SEQ ID NO: 1 wherein the isolated nucleic acid is less than 500 nucleotides long. The concept of "an isolated polynucleotide which hybridizes under stringent conditions to a nucleotide sequence comprising X nucleotides of SEQ ID NO: 1 wherein the isolated nucleic acid is less than 500 nucleotides long" does not appear to be part of the originally filed invention. Therefore, "an isolated polynucleotide which hybridizes under

stringent conditions to a nucleotide sequence comprising X nucleotides of SEQ ID NO: 1 wherein the isolated nucleic acid is less than 500 nucleotides long" constitutes new matter.

With respect to Claims 23-24, a careful examination of positions 2188-2328 of US Pat. 5942393 differs from 2754-2894. At position 2200 of the patent, a "T" is present. However, the corresponding nucleotide at position 2766 is a "G." Thus, there specification appears to have entered new matter with respect to the issued patent.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 23, 25, 27, 29, 31, 33, 35, 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to "an isolated polynucleotide that hybridizes under stringent conditions to a nucleotide sequence comprising X nucleotides of SEQ ID NO: 1 wherein the isolated nucleic acid is less than 500 nucleotides long."

The specification teaches a genomic sequence for the gene for MTase and indicates the location of exons in the polynucleotide. The specification teaches "the presumed exons are underline; presumed introns are indicated by one or more "N" substitutions for bases in the polynucleotide sequence." Example 1 teaches a test for MTase Catalytic activity in a sample (page 23).

The instant claims are broadly drawn to encompass variants and mutant within exons, which have not been described. The claims are directed to hybridization language. The single example in the Written Description Guidelines, namely Example 9, is directed to high stringency conditions which are 6XSSC and 65 degrees Celsius. Example 9 also requires a particular activity. Therefore, unlike Example 9, there is no actual reduction to practice of the claimed invention, clear depiction of the claimed invention in the drawings or a complete detailed description of the structure. There is no known or disclosed correlation between the function of MTase and the structure of the non-described regulatory elements and untranslated regions of the gene. There is no additional disclosure of physical and/or chemical properties. Weighing all factors in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of nucleotide sequence which hybridizes under stringent conditions to a nucleotide sequence comprising X nucleotides of SEQ ID NO: 1 wherein the isolated nucleic acid is less than 500 nucleotides long.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 23-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 9 of U.S. Patent No. 5,942,393, August 24, 1999. Although the conflicting claims are not identical, they are not patentably distinct from each other because the sequence recited in Claim 7, 9 of the '113 application, having the nucleotide sequence shown in SEQ ID NO: 1, or comprising only the exon coding regions of the nucleic acid sequence of Figure 1 would hybridize under stringent conditions to an exon of SEQ ID NO: 1. In the event that the new matter rejection is overcome, the double patenting rejection over the instant claims would be appropriate.

Response to Arguments

The response traverses the rejection. The response asserts, that in the event that the rejection is maintained, a terminal disclaimer will be filed. Thus for the reasons above and those already of record, the rejection is maintained.

Conclusion

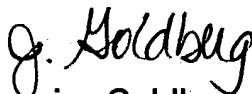
8. **No claims allowable.**

Art Unit: 1634

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571)272-0743. The examiner can normally be reached Monday-Friday from 6:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196. After January, the receptionist may be reached at (571)272-0507


Jeanine Goldberg
Patent Examiner
January 23, 2004